No. 83-196

In The

Supreme Court of the United States

October Term, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Appellant,

vs.

MONSANTO COMPANY,

Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

BRIEF OF THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, THE AMERICAN PUBLIC HEALTH ASSOCIATION, AND THE SOCIETY FOR CLINICAL ECOLOGY AS AMICI CURIAE IN SUPPORT OF APPELLANT

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INTERESTS OF AMICI*

The American Association for the Advancement of Science ("the Association") was founded in 1848 and incorporated in 1874. Its objects are to further the work of scientists, to facilitate cooperation among them, to foster scientific freedom and responsibility, to improve the effectiveness of science in the promotion of human welfare, and to increase public understanding and appreciation of the importance and promise of the methods of science in human progress.

* All parties have consented to the submission of this brief. Written letters of consent will be on file with the Clerk.

The interest of the Association in this case is to secure those essential conditions required to preserve integrity, accountability and responsibility in the exercise of scientific judgments in regulatory proceedings affecting public health and safety. The standards of scientific responsibility require the bases for scientific claims or assertions to be disclosed in a manner conducive to fully informed and open examination and evaluation. This case presents issues that affect in a fundamental way the Association's concerns for the preservation and integrity of scientific knowledge and the full use of that knowledge in the administration of regulatory powers involving health and safety.

The American Public Health Association ("APHA"), a non-profit organization founded in 1872, is the oldest and largest professional public health society in the world, with a combined national and affiliate membership of over 50,000 health professionals. APHA works to promote the health of the American people by encouraging a safe and healthful environment, launching public health education programs, advancing the availability of health services, and publishing numerous materials reflecting developments in public health, including dissemination of environmental information.

APHA is concerned about the potential hazards to humans and the environment posed by the use of pesticide chemicals. Increased public education about the dangers of pesticides is crucial in order to minimize these hazards. Public disclosure and peer review of pesticide health and safety data, in particular, is essential to protect humans and the environment.

The Society for Clinical Ecology ("the Society") is a national non-profit organization of physicians whose practices include treating patients with chronic and acute sensitivities to foods, chemicals and other allergenic substances. Members of the Society stress a very comprehensive environmental analysis of the etiology of their patients' afflictions. They test their allergic patients for a wide range of possibly offending substances. Their testing and treatment modalities are based on the most modern understanding of the human immune system and consequently are very successful.

Members of the Society find an increasing number of their patients to be allergic to various chemicals and particularly to both commercial and domestic pesticides. Many of their patients have become extremely sensitive to a host of substances as a result of varying exposures to pesticides, due to a phenomenon called immune function disregulation. Some have become so sensitive as a result of contact with pesticides that their ability to move freely in modern society has become severely limited.

The members of the Society for Clinical Ecology treat the victims of pesticide poisoning. In order for them to adequately treat these patients, it is essential for these doctors to be able to have access to the data involved in the pesticide regulatory decision-making process of the United States Environmental Protection Agency. It is also important for this same regulatory process that it benefit from the clinical experience of these doctors, who know first-hand what harm various pesticides can cause, even to persons with no previous histories of chemical sensitivities.

SUMMARY OF ARGUMENT

This appeal raises the critical issue of whether the public may have access to the health and safety studies used by the United States Environmental Protection Agency (EPA) to make pesticide regulatory decisions. Public disclosure and independent peer review of data are essential to ensure the integrity and validity of scientific research. Public disclosure of research results is also a fundamental norm in our scientific and political communities.

The district court's holding creates an anomalous situation in which the data relied upon to make crucial pesticide regulatory decisions are exempt from the public disclosure and peer review processes that operate in the broader scientific community. There are numerous instances in which EPA's closed regulatory scheme has failed to reveal fraudulent and inaccurate pesticide data, resulting in serious risks to public health and the environment. Public disclosure of such data would increase the likelihood of detecting and correcting regulatory errors through the peer review process. Congress amended the federal pesticide law in 1978 in recognition of this problem, and its decision to allow public disclosure of health and safety data was well within its constitutional powers and should not be overturned.

ARGUMENT

I. Public Disclosure And Peer Review Are Essential To Ensure The Integrity And Objectivity Of Scientific Research.

In order to promote the integrity and objectivity of scientific research, the scientific community relies heavily

on an internal, "self-policing" system known generically as "peer review." Through this process, independent scientists review and criticize the procedures, data analyses, and conclusions of scientific research before reports of the results are published or otherwise relied upon. The process can continue after publication as other scientists subject the results to the ultimate test of reproducibility. Peer review allows for the expression of a broad spectrum of theories and viewpoints to ensure scientific accuracy and objectivity. Without full public disclosure of the research methodology, raw data and results, however, the peer review process cannot operate effectively. The district court's judgment effectively precludes this process from occurring at all.

The peer review process in the scientific community embodies at least three distinct checks on reliability and validity of results.[1] First, applications for funding and approval of a project are carefully reviewed and assessed by rotating panels of advisers prior to project approval. Second, scientific journals request independent "referees" to measure the finished research products against scientific standards of quality and acceptability, to determine whether the research merits publication. Third, assuming the research passes these tests and is published, it is subject to an endless informal review process in which

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[1]See, e. g., *Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigation and Oversight of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 33-35 (1981) (statement of Donald S. Fredrickson, M.D., Director, National Institutes of Health) (hereinafter cited as *Biomedical Research Hearings); id.* at 166-67 (testimony of Dr. William F. Raub, Associate Director, National Institutes of Health); W. Broad & N. Wade, *Betrayers of the Truth* 17-18, 61-62, 89 (1982).

the work is read, considered, tested and at times replicated to ensure accuracy. Throughout, the process is characterized by full public disclosure of the techniques used and the results obtained. Openness is the essential ingredient for this time-honored process.

Public disclosure and peer review of data serve a number of critical functions in the scientific community and in our political system. Perhaps the most important application of peer review is in the regulatory framework where scientific decisions are made and reviewed. In this context, disclosure of the factual basis for regulatory decisions is essential to allow informed public participation and to promote careful and balanced decision-making. Secrecy, on the other hand, impugns the integrity of the decision-making process.

First and foremost, peer review is the most basic and effective means for ensuring accuracy in science. There can be little dispute that peer review and public disclosure of data have played a critical role in weeding out bad science from good science. Robert Merton, a recognized authority in the sociology of science, has attributed the rarity of fraud in science to "certain distinctive characteristics of science itself. Involving as it does the verifiability of results, scientific research is under the exacting scrutiny of fellow experts. . . . [T]he activities of scientists are subject to rigorous policing, to a degree perhaps unparalleled in any other field."[2] According to Dr. Philip Handler, former President of the National Academy of Sciences, "[t]he system succeeds in policing itself as it

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[2]R. Merton, "The Normative Structure of Science," in *The Sociology of Science* 266, 276 (1973).

does . . . not so much out of extraordinarily intrinsic honesty of those individuals who elect careers in science, but out of the fact that the entire system operates on the record."[3] It is no exaggeration to say that "[t]he greatest protection in science is the critical review and analysis of the published data and procedures by the scientist's peers."[4]

In addition to the functional, self-policing role played by peer review, full disclosure of techniques and results is a basic element in the scientific method. "The scientific method requires that all research work be open to critical examination and testing by researchers in the field."[5] According to ethicist Sissela Bok, the norm of openness in science springs "from a recognition of the damage that secrecy can do to thinking and to creativity, and thus to every form of scientific inquiry."[6] As stated by Donald Kennedy, then-Commissioner of the Food and Drug Administration (FDA):

> [The peer review] system is at the heart of the scientific process; it is a fundamental requirement of science that the hypotheses and conclusions of one

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[3] *Biomedical Research Hearings, supra* note 1, at 13.

[4] *Id.* at 66 (testimony of Dr. Ronald Lamont-Havers, Director of Research, Massachusetts General Hospital). *See generally, id.* at 65-68; *id.* at 83, 90 (testimony of Dr. Philip Felig, Yale School of Medicine); *id.* at 353-55 (testimony of Dr. Patricia Woolf, Princeton University); R. Merton & H. Zuckerman, "Institutionalized Patterns of Evaluation in Science," in *The Sociology of Science, supra* note 2, at 460-96.

[5] Pigman & Carmichael, "An Ethical Code for Scientists," 111 *Science* 643, 645 (1950).

[6] S. Bok, *Secrets: On the Ethics of Concealment and Revelation* 155 (1982).

scientist be subjected to public examination, criticism, and debate by other scientists before their validity is accepted. Such public comment depends on the availability of the analytical and empirical bases for the hypotheses and conclusions. If the underlying procedures and data cannot be examined by others, the scientific community cannot be confident of, nor eventually accept, the validity of the conclusions reported by the discoverer. *Secrecy is antithetical to good science.*[7]

Full disclosure of scientific research is necessary for scientific progress and innovation. Sociologist Bernard Barber has argued that "informal discussion among scientists of new work and new ideas" is "essential to all scientific innovation."[8] Secrecy "restricts the dissemination of new and possibly important techniques,"[9] both within the scientist's own field and within related fields.

Restrictions on public disclosure and review of data may not only impede advances in theoretical science, but may also preclude efforts to protect public health. As stated by the President's Science Advisory Committee in 1973, "[n]ot allowing the academic research community access to the retained results of [drug] safety testing is believed to have adversely affected progress in the understanding of the presence or absence of unfortunate ef-

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[7]Letter from FDA Commissioner Donald Kennedy to Senator Edward M. Kennedy (May 5, 1978), *reprinted in Drug Regulation Reform Act of 1978: Hearings on S. 2755 Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 2d Sess. 841, 842 (1978) (emphasis added) (hereinafter cited as Kennedy Letter).

[8]B. Barber, *Science and the Social Order* 91 (1952).

[9]W. Hagstrom, *The Scientific Community* 91 (1965).

fects of chemicals on people."[10] The concerns of groups like the March of Dimes with respect to limitations on free disclosure and peer review are worth emphasizing:

> The March of Dimes believes that putting a restriction on public information would severely limit the free exchange of scientific thought; even decrease the amount of scientific research so often fostered by this process of peer review. Limiting research will postpone, if not prevent, the discovery of causes and cures for the many birth defects which still afflict our infants and children. It may expose the unborn to harmful chemicals because these chemicals cannot be subject to peer review by the scientific community.[11]

Public disclosure of health and safety data is particularly important in a democratic political system. It is "a basic principle of our political system . . . that people affected by governmental decisions have a right to know the basis on which they are made."[12] Barring public scrutiny of the information underlying regulatory decisions removes a vital check on governmental policymaking.

> The secrecy of technological information is incompatible with the public policy function of a democracy. In our elective system, in the absence of public debate, there is no certainty that policy-making officials will possess the competence required for wise decisions or that they will even understand what elements of information are important. Moreover, even assum-

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[10]President's Science Advisory Comm., Panel on Chemicals and Health, *Report on Chemicals and Health* (1973), *reprinted in* Kennedy Letter, *supra* note 7, at 842.

[11]Letter from March of Dimes to Members of Congress, quoted at 128 Cong. Rec. H5687 (daily ed. August 11, 1982) (Rep. Daschle).

[12]Kennedy letter, *supra* note 7, at 841.

> ing the wisdom of policy-making officials, sound policy results from the careful examination of facts by the people of a nation in light of their diverse training and interests. Secrecy prevents the discussion necessary to such examination.[13]

Even if individual members of the public only rarely request to see the health and safety data that federal regulatory agencies collect, public availability of that data plays an important legitimizing role. The fact that any independent scientist may at any time scrutinize carefully the results of tests that support a product's license makes the safety-related decisions of the regulatory agency much more acceptable to the affected public. Failure to allow such scrutiny, on the other hand, breeds skepticism and ultimately contempt for the regulatory process.

II. Public Disclosure Of Data Is Particularly Important In The Pesticide Regulatory Process In Order To Ensure Protection Of Public Health And Safety.

In contrast to the open nature of most scientific research, the regulatory framework in which pesticide health and safety data are generated and analyzed lacks the multiple checks and balances of an open peer review system. Since the pesticide industry itself sponsors nearly all of the research, the initial peer review process of scrutinizing applications for government funding is entirely circumvented. The resulting studies are rarely published, thereby precluding independent scientists from reviewing or attempting to replicate the work. If the studies submitted to EPA may not be disclosed, the data and test methodology never enter the normal peer review channels,

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[13]Berkner, "Secrecy and Scientific Progress," 123 *Science* 783, 786 (1956).

and therefore are not subject to scrutiny by independent scientists.[14]

Before allowing the use of a pesticide in the United States, EPA must engage in a rigorous risk-benefit balancing process to ensure that pesticides do not pose an unreasonable risk to humans or to the environment. In order to make a fully informed decision, EPA requires pesticide registration applicants to submit a variety of health and safety studies. Certain of these studies are used by the agency to assess the chemical's potential to cause adverse effects to humans including cancer, birth defects, nerve damage and genetic mutations.

The studies submitted to EPA consist primarily of the results of animal feeding and exposure tests. With few exceptions, these tests are conducted exclusively by the pesticide manufacturers and private laboratories under contract to them. Interpreting these tests is often extremely controversial. Reasonable minds can differ with respect to the nature of the observed results (raw data), the extrapolation of such results to humans and

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[14]A limited formal procedure for review of certain pesticide data does exist, but the process does not purport to substitute for independent peer review made possible by disclosure of data. *See* 7 U. S. C. § 136w(e) (1980). EPA's procedures provide for mandatory peer review only of those studies sponsored or undertaken by the agency, not of the vast majority of studies prepared by industry. Industry studies considered by the agency to be "pivotal" will only be peer reviewed "at the discretion of the agency;" whereas other "supporting studies . . . will generally not be peer reviewed." As a result, "there will be many important studies done by industry and by the public sector which the Agency will not submit for peer review." *See* 46 Fed. Reg. 61502-05 (Dec. 17, 1981). Moreover, the formal review process is limited to a select group of scientists and does not provide for full public disclosure and independent scientific review of data.

the regulatory implications of the results. Industry scientists, not surprisingly, generally advocate an interpretation that will allow their products to be marketed with a minimum of regulatory restrictions.[15] With unsettling frequency, the health and safety data that the pesticide industry provides to support its products have been found to be misleading and, in some cases, entirely fraudulent.

Unless the health and safety studies are made available to the public, the only opportunity for scientific review is by agency personnel. Given staff and funding limitations, however, agency scientists cannot be expected to evaluate thoroughly every health and safety study submitted on behalf of a pesticide. Moreover, a one-time agency examination of completed research cannot substitute for review by a diverse group of independent peers over a period of time, which would be possible if data were disclosed. When agency scientists are essentially confined to dialogue with industry scientists—who of necessity must assume an advocacy role—they are deprived of the scientific pluralism that is crucial to informed scientific judgment.

Until 1978, the process of pesticide testing was effectively shielded from any open peer review. Under the rubric of "trade secrets," the pesticide industry successfully obtained a closed system which precluded public scrutiny of its health and safety data. The history of this closed process is replete with incidents in which the registrations of widely-used toxic pesticides have been based upon false and, in some cases, fraudulent data.

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[15]See McGarity & Shapiro, "The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Practices," 93 *Harv. L. Rev.* 837, 840-41 (1980).

When government scientists cannot participate in the normal system of peer review that scientists use to evaluate their research, it significantly hampers their ability to make judgments necessary to protect the public.

Unlike the numerous opportunities for peer review in the scientific community, there has been virtually no independent scientific scrutiny of the health and safety data that often serve as the sole basis for EPA's pesticide regulatory decisions. As a result of this closed process, a number of serious problems have remained undetected for years, ranging from scientific inaccuracies, to incorrect or biased interpretations, to outright fraud or fabrication of the data. The following examples demonstrate the strong public interest in full disclosure and peer review of pesticide health and safety test data.

Heptachlor. EPA's decision to register a pesticide for a particular use depends almost exclusively on a one-time review of the health and safety data submitted by the pesticide manufacturer. After a product is approved, the agency rarely has the time and resources to re-evaluate the original test data in light of changing facts or newer scientific evaluational criteria. In some cases, deficiencies in the tests submitted in support of a pesticide have only been discovered years after the pesticide was registered.

In the case of the pesticide heptachlor, an earlier industry interpretation of data remained unexamined for years in the government's files, even though the scientific community's interpretational criteria had changed significantly. Heptachlor was initially registered based on the manufacturer's data that purported to show that the

chemical did not cause cancer in laboratory animals. Fifteen years later, a re-evaluation of the same data by independent scientists—supported by new tests—indicated that heptachlor was carcinogenic. Between the initial approval of heptachlor and its final removal from the market fifteen years later, the public was exposed to high levels of the chemical.[16] The manufacturer was indicted in 1977 for concealing key scientific results on the carcinogenicity of heptachlor. However, the case was dismissed on procedural grounds.

Temik. Without mandatory disclosure of pesticide data, the agency may fail to obtain key information that would enable it to assess the test data more thoroughly. In the case of the pesticide Temik(R), agency scientists overlooked the narrow and misleading assumptions underlying one key study. Based on these limited assumptions, the study erroneously predicted that use of the product was safe.

The carbamate pesticide Temik or aldicarb, licensed for use in the mid-1960s, is one of the most acutely poisonous substances registered for use on food. At that time, the industry-submitted tests allegedly demonstrated that after application to the soil, Temik would biodegrade to a harmless substance before reaching the groundwater. However, in 1979, Temik was detected at dangerous levels in the groundwater of some areas on Long Island.[17] Long Island's groundwater is the sole source of drinking water

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[16] *Id.* at 841.

[17] *See, e. g.,* "Story of 'Safe' Pesticide Ends as Classic Case of Misuse," *New York Times,* March 4, 1980, p. C1.

for nearly three million people. The manufacturer later admitted that its groundwater leaching studies had failed to analyze the effects of pesticide use in regions, like Long Island, with sandy soils and shallow groundwater. Since 1979, Temik has also been detected in groundwater and drinking water in Florida, Maine, Wisconsin, California, North Carolina, Virginia and Arizona.

In retrospect, many are surprised that government officials did not foresee the Long Island groundwater contamination by Temik, given the widespread knowledge about Long Island's geologic composition and the facility of numerous substances to percolate or leach through these soil types. However, EPA scientists were largely isolated from routine consultation with the scientific community, because they could not disclose the data on Temik's environmental fate. It is entirely plausible that scientists or members of the public with knowledge of local conditions could have alerted EPA to the flawed assumptions of the industry's study, thereby avoiding a serious public health hazard.

Industrial Bio-Test Laboratories. Another problem resulting from the absence of peer review of pesticide data is that agency scientists may not be capable of weeding good science from bad science. This inability may be the result of unreasonable work loads or of the lack of routine communications with independent scientists. The most glaring example of this problem involves one of the nation's oldest and largest independent laboratories, Industrial Bio-Test Laboratories (IBT).

In 1976, Dr. Adrian Gross, an FDA investigator at the time, became suspicious of several IBT studies be-

cause they seemed to prove the safety of pesticide and drug products a bit too convincingly. When Dr. Gross reviewed some of IBT's raw data he discovered an unusual term, "TBD," or "too badly decomposed," which was used to indicate that animals had died and rotted in their cages before yielding any useful information. The fact that the animals were so poorly observed did not speak well of the carefulness and thoroughness of IBT's research efforts. Yet, the results submitted to the agency did not report this shoddy technique. Dr. Gross' observations led to other investigations of IBT that revealed other examples of falsified research, including substituting fresh test animals for ones that died during the course of an experiment, transferring data from one IBT experiment to another study, and using data from a study at another lab in IBT reports.[18] As a result, IBT's top officials were recently convicted in federal court of conducting fraudulent research with respect to four chemicals.[19]

The criminal conviction, however, represents only the tip of the iceberg. In July 1983, EPA released a long-awaited report summarizing the results of a seven-year investigation of IBT. The report uncovered what may be the most extravagant use of fraud in scientific history. The data in the report (and in an updated version) indicate that only three percent of the 803 IBT tests on chronic health effects (cancer, birth defects, adverse reproductive effects, nerve damage and genetic mutations) are val-

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[18]See Schneider, "Faking It: The Case Against Industrial Bio-Test Laboratories," 4 *The Amicus Journal* 114 (Spring 1983); Marshall, "The Murky World of Toxicity Testing," 220 *Science* 1130 (1983).

[19]*United States v. Calandra*, No. 81-CR-325 (N. D. Ill. 1980).

id and sufficient to support pesticide registration.[20] The validity of a number of IBT studies still remain to be determined. In the meantime, between 140 and 182 separate pesticide active ingredients registered with IBT data remain in use.[21] While the safety of these chemicals is unknown to EPA, the public continues to be exposed to them as residues in their food and drinking water, in home use pesticide products, in the workplace, and throughout the environment.

It is impossible to know whether the fraud and inaccuracies in the IBT studies would have been uncovered sooner if the public had been given access to the raw data underlying these studies as they were reported to EPA. The likelihood that the studies would have been subject to peer review, however, would have been a powerful disincentive to falsify and cheat. Without the threat of full public disclosure, the company risked detection only by overworked agency scientists, a gamble it was willing to take.

Harvade. The previous examples have demonstrated that EPA is incapable of ensuring the integrity of health and safety data on its own. Perhaps the most egregious example of this failure is the recent discovery that some EPA scientists reviewing industry-submitted studies have merely cut and pasted summaries from those studies onto agency stationery, and labeled the re-typed document,

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[20]EPA, Office of Pesticide Programs, *Summary of the IBT Review Program* (July 1983); EPA, Office of Pesticide Programs, *IBT Tracking System Report* (August 30, 1983).

[21]The EPA reports contain a number of inconsistencies; therefore, it is difficult to determine the precise number of pesticides registered with IBT data.

"Review of. . . ." These cut-and-paste reviews suggest that overworked agency scientists have uncritically accepted the accuracy, completeness, and conclusions of the industry-submitted data.[22]

One example of this treatment is the chemical Harvade. The agency toxicologist assigned to Harvade reviewed the studies by the cut-and-paste method. Subsequently, the chemical was approved by EPA, and it went on sale in 1982. Several weeks after its approval, another agency scientist spotted discrepancies between the earlier review and his own findings on Harvade's toxicity. Shortly thereafter, the cut-and-paste copying was discovered and the chemical is now being re-evaluated. In the meantime, Harvade remains on the market.[23]

III. Congress' Decision To Allow Public Disclosure Of Pesticide Data Should Not Be Overturned.

There is every reason to believe that public disclosure and peer review would promote the integrity and objectivity of scientific studies in the context of pesticide regulatory decision-making. Dr. Donald Kennedy has emphasized that the "validity and credibility of [regulatory]

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[22]*See Hearings on H. R. 3818 Before the Subcomm. on Dep't Operations, Research, and Foreign Agriculture of the House Comm. on Agriculture*, 98th Cong., 1st Sess. (Nov. 2, 1983) (statement of William D. Ruckelshaus, EPA Administrator).

[23]EPA has contracted with Battelle Memorial Institute to conduct an analysis of its Office of Pesticide Programs. Preliminary results indicate that cut-and-paste review are much more prevalent than originally thought. Six EPA staff members have been reassigned to tasks other than data review until the Battelle report is completed. *See* "HED Reviewers Reassigned Because of 'Cut and Paste' Audit Results," *Pesticide and Toxic Chemical News*, pp. 15-16 (October 5, 1983).

decisions can be assured only if the underlying data and conclusions are subject to the same critical scientific process that applies to other scientific matters. . . . The opportunity for review by scientists outside the agency will provide a valuable additional incentive for [industry] to produce the best and most reliable data."[24]

Members of Congress and independent scientists have both stressed the importance of full disclosure and peer review of pesticide data in order to protect public health and the environment. As stated by Representative Schneider in opposing a bill that would have limited public disclosure of pesticide data, "[w]hen dealing with potentially hazardous chemicals, we must do everything in our power to facilitate peer review of testing methods, not set up roadblocks."[25] The American Association for the Advancement of Science has urged Congress to retain full public disclosure, arguing that "[i]f independent scientific verification of [pesticide] data . . . is foreclosed . . . , both public and scientific accountability could be degraded unacceptably."[26] Similarly, a group of over forty independent scientists has emphasized that, without public disclosure and peer review of pesticide data, "there is no way of knowing whether testing on these substances has been conducted thoroughly and the data honestly pre-

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[24]Kennedy Letter, *supra* note 7, at 842-43.

[25]128 Cong. Rec. H5683 (daily ed. Aug. 11, 1982).

[26]Letter from William D. Carey, Executive Officer, American Association for the Advancement of Science, to Representative Elliott H. Levitas (July 30, 1982), *reprinted in* 128 Cong. Rec. H5682 (daily ed. Aug. 11, 1982).

sented to the agencies charged with protecting the public's safety."[27]

In recognition of the importance of independent and public review of EPA's pesticide decision-making, Congress amended the pesticide laws in 1978 to provide for public disclosure of health and safety data. Douglas Costle, then-Administrator of EPA, testified in support of the 1978 public disclosure amendments that they properly recognize "the valuable contribution to Agency decision-making that can come from independent public review and comment upon the base of information on toxicity . . . and other characteristics of pesticides to which the public may be exposed."[28] Senator Kennedy emphasized that public disclosure is of "particular significance" in light of EPA's prior failure to ensure that pesticides are supported by complete and accurate data.[29] Public disclosure of pesticide data reflects Congress' recognition not only of the importance of peer review,[30] but also of the "legitimate right of the public to know the basis for agency decisions."[31]

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[27]Letter to Members of Congress from Marvin S. Legator, Ph.D., and 46 other scientists (July 19, 1982), *reprinted in* 128 Cong. Rec. H5681-82 (daily ed. Aug. 11, 1982).

[28]H. R. Rep. No. 663, 95th Cong., 1st Sess. 52 (1977).

[29]123 Cong. Rec. 25711 (1977).

[30]*See, e. g.*, 128 Cong. Rec. H5679-80 (daily ed. Aug. 11, 1982) (Rep. Levitas); *id.* at H5683 (Rep. Schneider); *id.* at H5684 (Rep. Weaver); *id.* at H5687-88 (Rep. Gore); *id.* at H5689 (Rep. Scheuer).

[31]H. R. Rep. No. 663, 95th Cong., 1st Sess. 18, 42 (1977). *See also* S. Rep. No. 334, 95th Cong., 1st Sess. 13 (1977); 123 Cong. Rec. 36008 (1977) (Rep. Fithian); 128 Cong. Rec. H5679 (daily ed. Aug. 11, 1982) (Rep. Levitas).

The 1978 amendments have allowed scientists and public interest groups, for the first time, to review the crucial health and safety data underlying the registrations of many widely used pesticides. The district court's decision, if upheld, would halt peer review in its tracks. Such a holding would create, once again, an anomalous situation in which pesticide health and safety data are excluded from the open peer review process used to ensure the integrity and objectivity of nearly all other scientific studies—even though, as recognized by Representative Scheuer, Chairman of one House Subcommittee with jurisdiction over pesticide research, "scientific peer review of pesticide research is absolutely necessary if the health and environment are to be protected."[32]

CONCLUSION

For the foregoing reasons, the decision of the district court should be reversed.

Respectfully submitted,

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[32] 128 Cong. Rec. H5689 (daily ed. Aug. 11, 1982).